In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-1418V
(not to be published)

K.N. *and* C.L., *on behalf of J.J.N.*,	*	
	*	Special Master Corcoran
	*	
	*	Filed: February 4, 2019
Petitioners,	*	
v.	*	
	*	Dismissal of Petition; Vaccine
SECRETARY OF HEALTH	*	Act; Denial Without Hearing.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

K.N. & C.L., pro se, Brockton, MA.

Voris E. Johnson, U.S. Dep't of Justice, Washington, D.C. for Respondent.

DECISION DISMISSING CASE FOR INSUFFICIENT PROOF[1]

On October 3, 2017, K.N. and C.L. filed a petition seeking compensation under the National Vaccine Injury Compensation Program on behalf of their minor son, J.J.N.[2] Petitioners allege that certain childhood vaccines that J.J.N. received on September 24, 2014, caused him to suffer from seizures, aphasia, and developmental delays. Am. Pet. at 1–2, filed Feb. 14, 2018 (ECF No. 14). They also maintain that additional vaccines J.J.N. received on November 25, 2014, precipitated an encephalopathy, and that he was also subsequently harmed by another vaccine administered to him on January 6, 2018. *Id.* at 1, 3–4. The medical records filed in this case

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

establish that J.J.N. has been diagnosed with an autism spectrum disorder ("ASD"). *See* Ex. 1 at 1, filed Oct. 3, 2017 (ECF No. 1-1).

The case was initially assigned to Special Master Gowen, but then transferred to me in May 2018. By that time, the Petitioners had filed an amended petition and a large number of medical record documents. *See generally* Am. Pet.; Exhibits 1–16; Exhibit 18; Exhibits 21–23, filed Feb. 14, 2018 (ECF Nos. 14-4–14-23).[3] After reassignment, I held a status conference with the parties in July to discuss the nature of Petitioners' allegations. At that time (and after I had conducted an initial review of the claim and documents offered in its support), I explained to Petitioners that the claim faced considerable obstacles. *See generally* Order, dated July 16, 2018 (ECF No. 25). In particular, I noted that (a) the record did not suggest that J.J.N. had experienced an "encephalopathy" leading to developmental problems, and (b) it appeared that the Petitioners wished to argue that J.J.N.'s autism was vaccine-caused, even though such claims have never once succeeded in the Vaccine Program (at least as non-Table claims in which causation had to be established). *Id.* at 1–2.

Despite my initial misgivings about the substantive strength of the claim, however, I informed the Petitioners that (because in a few rare circumstances claimants have succeeded in establishing that a vaccine induced a Table-defined encephalopathy that produced developmental regression or plateauing) I would afford them the opportunity to file whatever medical records they proposed could establish this had occurred—although I also invited Respondent (in his then-yet-unfiled Rule 4(c) Report) to seek the claim's dismissal. Order at 2–3.

Respondent did in fact request dismissal as anticipated. *See* Rule 4(c) Report, dated Aug. 31, 2018 (ECF No. 26) ("Mot."). Petitioners thereafter filed a response opposing the motion (although they filed no additional medical records even after my warning in July). *See* Petitioners' Response, dated Dec. 26, 2018 (ECF No. 32) ("Opp."). I have now had the opportunity to review both filings, and in light of them plus the record, hereby (and for the reasons set forth below) dismiss the claim.

I. Brief Factual Summary

J.J.N. was born on June 19, 2013. Ex. 1 at 1 (ECF No. 14-4); *see generally* Ex. 2. Before receiving the vaccinations in question in this case, there were some vague preliminary signs (reflected in the medical record) that he might have developmental problems. For example, at his nine-month well-baby exam in February 2014, C.L. reported occasional hand flapping, although the exam did not conclude at this time that J.J.N. was in fact autistic or developmentally delayed.

[3] The exhibits filed in this case were not numbered consistently. Two documents were filed as Exhibit 1 (ECF No. 1-1 and ECF No. 14-4), and no Exhibit 17, 19, or 20 was ever filed. For the sake of clarity, references to either Exhibit 1 will include the ECF number throughout this Decision.

Ex. 8 at 15–16. Ear flapping was reported at a sick visit that April. Ex. 9 at 6. However, no treater determined that such behaviors were true warning signs prior to the vaccinations in question.

On September 24, 2014, J.J.N. (then fifteen months old) was seen for a well-baby visit, at which time her received the first vaccines at issue (inactivated polio virus, pneumococcal conjugate, haemophilus influenzae, and influenza). Ex. 8 at 18–19. There is no recorded reaction to these vaccinations; indeed, J.J.N. had sick visits to his pediatrician several times in the next six weeks for a variety of conditions (including a tick bite in early October), but there is no report of a reaction independent from the primary reasons for seeking treatment on each occasion. *See, e.g.*, Ex. 9 at 13–14 (October 1, 2014—tick bite), 15–16 (October 3, 2014—viral illness), 17 (November 3, 2014—diarrhea and fever).

On November 5, 2014, at a follow-up appointment to assess the status of J.J.N.'s recovery from the tick bite the month before, C.L. reported to the pediatrician her concern that J.J.N. had become fussy, would not make eye contact (and had not been doing so for several weeks), and was writhing intermittently as if in pain. Ex. 9 at 18. His grandmother was also concerned that he seemed withdrawn and had not been making eye contact for three to four weeks. *Id.* The exam was normal, however, and J.J.N. was noted merely to have experienced "fever" and "behavioral change." *Id*; *see also* Ex. 7 at 2.

Less than two weeks later, on November 13, 2014, J.J.N. returned to his pediatrician with reports that he might have been experiencing seizures, as well as other behaviors often associated with developmental difficulties (for example, walking on tiptoes). Ex. 9 at 21–22. C.L. noted at this time that she had called a developmental pediatrician, who recommended a neurological evaluation. *Id.* She repeated such concerns at the end of the month, on November 25, 2014, when J.J.N. was taken for his eighteen-month well-baby visit. Ex. 8 at 21–22. At that time J.J.N. received several additional vaccines (measles-mumps-rubella ("MMR"), varicella, diptheria-tetanus-acellular pertussis ("DTaP"), and another flu vaccine). *Id.*

J.J.N. received the neurologic evaluation that had been previously recommended on December 11, 2014, when he was seen by Eugene Roe, M.D., and Sara Delvecchio, N.P., at Boston Children's Hospital Weymouth Neurology clinic. *See generally* Ex. 12 at 1–4. The record from this visit references "a history of two episodes of altered consciousness" beginning in early October 2014, with a second in the first half of November; the first was observed by C.L. and seemed like a seizure, while in the second he was found limp and face down after jumping on an indoor trampoline. *Id.* at 1. C.L. also reported observing eye fluttering "over the past couple of months" and an inability to make eye contact. *Id.* at 2. She squarely informed these treaters of her concern that J.J.N.'s symptoms constituted "the presentation of autism." *Id.* She made no mention of the vaccinations J.J.N. had received in September or November as having any relationship in her understanding to his symptoms, although she did mention the early October tick bite. *Id.*

The exam of J.J.N. revealed no obvious problems but did confirm his difficulty in maintaining eye contact. Ex. 12 at 2–3. Nurse Practitioner Delvecchio recommended an EEG, MRI, and early intervention for language development, as well as a genetics evaluation (based on reported attention deficit/hyperactivity disorder running in the family). *Id.* at 3. The prescribed EEG was performed in January 2015 and came back normal. Ex. 21 at 1–3. In addition, an infectious disease work-up (noting that J.J.N. had tested negative for Lyme disease after the early October tick bite) was also negative, with the treaters who performed it informing Petitioners that there was no known link between autism and prior infection in any event. Ex. 13 at 1–2. The brain MRI performed at the end of January 2015, however, revealed a "highly unusual configuration of the corpus callosum." Ex. 6 at 1.

On March 4, 2015, J.J.N. saw Nurse Practitioner Delvecchio for follow-up. Petitioners informed her that J.J.N.'s behavior issues and communication deficits were now heightened, leading her to deem them "strongly suggestive" of autism spectrum disorder, and to recommend that he receive specialized therapies aimed at treating ASD symptoms. Ex. 12 at 9–11. The medical record for the subsequent timeframe discloses Petitioners' consistent efforts to provide J.J.N. the care necessary to treat his developmental problems, but largely do not impact analysis of the present claim, and therefore are not further discussed.

II. Parties' Respective Arguments

As noted, Respondent requested the claim's dismissal in his Rule 4(c) Report. Mot. at 11. He argues that Petitioners' claim that J.J.N. experienced an encephalopathy after his November 2014 vaccinations fails because the medical record does not reveal facts that would support the Table definition of that term. *Id.* at 7–8 (citing 42 C.F.R. § 100.3(c)(2)(i)(A)(1)). In particular, (a) the record reveals that J.J.N. experienced a "decreased level of consciousness" (a requirement to establish encephalopathy under the Table) on two occasions *before* the November vaccinations—not after, and (b) there was no evidence of post-vaccination chronic encephalopathy either. *Id.* at 8. The Petitioners had also not demonstrated the nature of J.J.N.'s injury after the September 2014 vaccinations. *Id.* at 9–10. And to the extent the Petitioners sought recovery for J.J.N.'s developmental problems (whether or not they were deemed indicative of an ASD), the overwhelming majority of cases litigated in the Program since the time of the Omnibus Autism Proceedings (the "OAP")[4] had rejected any causal association between vaccination and ASD, including where a claimant alleged a non-Table claim based on a purported vaccine-induced encephalopathy. *Id.* at 10–11 (citations omitted).

[4] My July 2018 Status Conference Order discussed above includes a lengthy footnote addressing the history and ultimate disposition of the OAP cases. *See* Order at 1 n.1, dated July 16, 2018 (ECF No. 25).

Petitioners have opposed Respondent's motion, and in doing so make several fact arguments (although these arguments were not substantiated with additional records or other proof not previously filed in the case). Thus, looking at J.J.N.'s medical history prior to the September 2014 vaccinations, they maintain that he experienced a level of eczema as of the winter of 2014 (after receiving prior doses of the DTaP vaccine) recognized as an "autoimmune issue," suggesting that his alleged subsequent reactions to later doses may have been autoimmune in character as well. Opp. at 2 ¶ 5. They also claim that they sought to bring J.J.N. in for emergency medical treatment in early November 2014 for "meningitis, encephalitis, or something similar," but that the documented November 5th doctor's visit reflected in the existing medical record did not accurately record the alarming degree of his symptoms ("he was writhing in agony, arching his back"). *Id.* at 2 ¶ 7.[5] And Petitioners similarly maintain that after the November vaccinations, J.J.N. experienced "3 days of acute lethargy," again proposing that the contemporaneous record's failure to corroborate such allegations is attributable to those records being in error. *Id.* at 3 ¶ 9.

Based upon the above, Petitioners maintain that their claims are well-founded. They assert that prior Program case law involving the OAP or autism is not relevant because they do not seek to establish a relationship between J.J.N.'s vaccinations and autism (although they simultaneously maintain that his "severe neurologic injury" was sufficient for an autism diagnosis regardless). Opp. at 5 ¶¶ 23, 26. Rather, they maintain that his symptoms were precipitated by an encephalopathy, which began after the September 2014 vaccinations and was exacerbated by those received in November. *Id.* at 5 ¶ 24. J.J.N.'s purported eczema is evidence of an autoimmune intolerance to vaccination. *Id.* They also focus on his alleged reaction after the November 2014 vaccinations as sufficient to meet the Table's encephalopathy definitions. *Id.* at ¶ 28.

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of her vaccinations (in which case establishing causation-in-fact is not required), or (2) that he suffered an injury that was actually caused by a vaccine. *See* Sections 13(a)(1)(A) and 11(c)(1). Petitioners seeking to establish entitlement via a causation-in-fact must meet the three-prong test for such a claim set forth by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005).

The evidence filed in this matter does not establish the Table requirements for encephalopathy. I have discussed in prior cases the evidentiary burdens a petitioner must satisfy to establish a child experienced a post-vaccination encephalopathy. *See, e.g., Thompson v. Sec'y*

[5] This paragraph of Petitioners' Opposition also suggests an intent to file declarations substantiating these allegations, but none were ever filed.

of Health & Human Servs., No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017) (dismissing Table claim that post-vaccination encephalopathy occurred and resulted in ASD). Here, it is self-evident from the present record that these strict requirements are not met. The contemporaneous medical record establishes no evidence that (however legitimately alarming the symptoms may have been) J.J.N. experienced an acute (meaning sufficient to require hospitalization) or subsequent chronic encephalopathy after his September or November 2014 vaccinations. Indeed, J.J.N.'s instances of altered consciousness *preceded* the November vaccinations, further harming the argument that that date was the start of a Table encephalopathy, and the most alarming medical occurrence after the September vaccinations was the October tick bite. Petitioners' desire to vary what the existing records establish with their own recollections fly in the face of long-standing Program law holding that contemporaneous records are deemed accurate except in limited circumstances not established to be relevant here. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). And in any event, Petitioners did not file any such additional evidence, despite having had more than three months to act since the filing of Respondent's motion to dismiss.

The record is similarly unsupportive of Petitioners' non-Table claim that J.J.N. experienced a reaction to his September and November 2014 vaccinations—whether separately or together—culminating in the ASD symptoms he has experienced.[6] As noted, there is little in the record that would corroborate allegations of a post-vaccination encephalopathy after either vaccination date. The first concern expressed by Petitioners that J.J.N. might have an ASD is found in the November 5, 2014 record, which falls between the two vaccination events, but without any intervening evidence suggesting the early vaccinations led to this event and were then worsened after the November vaccinations. There is also no treater support for Petitioners' contentions, and some evidence that J.J.N. may have shown signs of developmental difficulties even before the September 2014 vaccinations.[7] All that remains is the fact that Petitioners' observations of J.J.N.'s symptoms led them to seek intervention *after* the September vaccinations, with follow-up (and more conclusive diagnoses of an ASD) occurring after the November vaccinations. This temporal association is not enough for a successful Program claim. *McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).

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[6] Petitioners' Opposition makes no mention of their prior assertion that J.J.N. experienced some kind of reaction after receiving the Hep A vaccine in January 2018, and I similarly find that the record is not supportive of a Vaccine Program award based upon such allegations.

[7] Petitioners' assertions that J.J.N. displayed a sensitivity to the DTaP vaccine, revealed in the winter of 2014 after receiving initial doses of it, and that this sensitivity reflects a propensity for an autoimmune response (which presumably occurred again after the November 2014 vaccinations) is also unsupported by the record. On May 20, 2015, J.J.N. saw Margaret Vallen-Mashinkien, M.D., an allergist. A history of reported eczema plus an instance of hives was provided, and the assessment was atopic dermatitis, allergic rhinitis, and recurrent bacterial infection. Ex. 18 at 5–6. No treater, however, linked any of the above to the DTaP vaccine or deemed it out of the ordinary, and there is nothing from the 2014 record that would suggest any eczema revealed at that time was vaccine-related.

Finally, Petitioners have not successfully distinguished this case from the many autism claims that have been litigated unsuccessfully in the Program. I noted in *Thompson* that non-Table claims alleging a vaccine-caused developmental problem (whether or not the petitioners agreed it was autism) decided since the conclusion of the OAP had uniformly failed. *Thompson*, 2017 WL 2926614, at *13 (citing *Wolf v. Sec'y of Health & Human Servs.*, No. 14-342V, 2016 WL 651858, at *15 (Fed. Cl. Spec. Mstr. Sept. 15, 2016)). The same is true for non-Table claims attempting to characterize developmental symptoms as the secondary result of a vaccine-induced encephalopathy. *Id.* at *13 (citing *Cunningham v. Sec'y of Health & Human Servs.*, No. 13–483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Aug. 1, 2016) *mot. for review denied*, 2017 WL 1174448, at *5 (Fed. Cl. March 22, 2017) (disregarding "petitioner's attempt to differentiate this case from other autism cases by creating this second step"—that post-vaccination developmental regressions can be attributed to a vaccine-induced encephalopathy even if there is no evidence of an encephalopathic reaction)). These cases underscore why proceeding with this case would be reasonable given the present record.

CONCLUSION

Under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on his claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1). In this case, there is insufficient evidence in the record for Petitioners to meet their burden of proof, especially given the nature of injury alleged. Petitioners' claim therefore cannot succeed and must be dismissed. Section 11(c)(1)(A).

Thus, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.[8]

IT IS SO ORDERED.

Brian H. Corcoran
Special Master

[8] Pursuant to Vaccine Rule 11(a), the parties may expedite judgment by filing a joint notice renouncing their right to seek review.